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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,843	11/02/1999	IAN S. ZAGON	13038	9285

7590 10/28/2004

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/431,843	ZAGON ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6,14-17 and 38* is/are pending in the application.

4a) Of the above claim(s) *4 and 15* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 38* is/are allowed.

6)☒ Claim(s) *3,5,6,14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/04 has been entered.

1. Formal Matters

A. The Amendment dated 3/4/04 has been entered into the record.

B. Claims 1, 3-6, 14-17 and 38 are pending in this application. Claims 4 and 15 have been withdrawn from consideration. Therefore, claims 1, 3, 5, 6, 14, 16, 17 and 38 are the subject of this Office Action.

C. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Answer to Traversal

A. Applicants argue that the antisense sequence can be determined once the sense sequence is disclosed and that they can affect the functions of the sense strand. Applicants further argue that the Examiner cannot base this restriction on differing class and subclass classification since a search of the sense would encompass a search of the other

These arguments have been considered, but are not deemed persuasive. First, the fact that the antisense can affect the function (e.g. down-regulate gene expression) of the sense strand is, respectfully, irrelevant. In fact, this supports the Examiner's position that these molecules are independent and distinct and have separate function (i.e. separate status in the art). While it is routine for a Group encompassing a sense strand to encompass the complement strand as well, the same does not hold true for antisense. An antisense molecule is not the same as a complement. As stated in the restriction in the action mailed 7/16/01, the polynucleotide encoding the protein and the antisense are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case the nucleic acids have characteristic

differences in their structure, as evidenced by the differing nucleic acid sequences. Polynucleotides can be used to produce proteins, whereas antisense is used to inhibit gene expression.

Though the addition of SEQ ID NOs would not overcome the restriction, it is noted that the claims do not recite SEQ ID NOs of the antisense. It is well-known in the art that simply using any complementary strand to the sense strand would not necessarily function as an antisense molecule. In other words, given the sequence of the sense strand, it would be undue burden for the Examiner to attempt to identify which sequences could possibly be used as antisense. There would literally be thousands of sequences from which to choose. Based on these arguments by the Examiner and the knowledge in the art, it should be obvious to even the most ordinarily skilled artisan that any challenge based on the assertion that the antisense is obvious over the polynucleotide (sense) sequence is misplaced. This restriction is, therefore, deemed proper and is made FINAL.

3. Specification

A. Figure 9 is objected to since the Brief Description of Drawings does not begin with "Figures 9A-D depict."

3. Claim Objections

A. Claim 5 is objected to since it depends from non-elected claim 4. Claim 16 is objected to since it depends from claim 5.

5. Claim Rejections - 35 USC § 101

A. The rejection of claims 1, 3, 5, 6, 14, 16, 17 and 38 under 35 USC 101 has been withdrawn in view of Applicants' cancellation of sequences other than SEQ ID NO:1, which has been shown to have a specific, substantial, well-established utility since it binds the opioid ligand, [Met5]-enkephalin (i.e. OGF).

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 1, 3, 5, 6, 14, 16, 17 and 38 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that the present invention has been shown to have a specific, substantial, well-established utility as seen above under 35 USC 101.

B. The rejection of claims 1, 3, 5, 6, 14, 16 and 17 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove reference to "fragments" and to recite exact hybridization conditions as well as to recite the functional limitation that the encoded receptors must bind OGF.

C. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim does not require the host cell to be isolated and, therefore, reads on gene therapy. It is recommended that the claim be amended to recite "An isolated host cell."

D. Claims 14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As suggested by the Examiner, Applicants have amended the claims to remove "pharmaceutical" from the preamble. However, upon further consideration, this claim is viewed as a "reach through" claim. It appears that Applicants are attempting to encompass methods of treatment using these polynucleotides. However, Applicants have not provided any guidance or working examples in the specification of the use of the polynucleotides of SEQ ID NO:1 for any therapeutic purpose, nor would it be predictable to the artisan how to use these polynucleotides for any therapeutic purpose.

*7. **Claim Rejections - 35 USC § 112, first paragraph – written description***

A. The rejection of claims 1, 3, 5, 6, 14, 16 and 17 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove reference to "fragments" and to recite exact hybridization conditions as well as to recite the functional limitation that the encoded receptors must bind OGF.

8. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 3, 5, 6, 14, 16 and 17 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The hybridization conditions recited in claim 3 and as disclosed on the paragraph bridging pages 13 and 14 of the specification, do not recite a wash step of "about 65°C," nor "about 0.1% SDS." Only the specific SDS concentration of 0.1 is disclosed and no specific wash temperature is disclosed. This is a new matter rejection.

9. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claim 3 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claim to recite the "full-length complement."

10. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn in view of the fact that Applicants have amended the claims to recite the functional limitation that the polypeptide binds OGF. None of the references teach this limitation, nor could the Examiner make a prima facie case.

11. Claim Rejections - 35 USC § 103

A. All rejections under 35 USC 103 have been withdrawn in view of the fact that Applicants have amended the claims to recite the functional limitation that the polypeptide binds OGF. None of the references teach this limitation, nor could the Examiner make a prima facie case.

12. Conclusion

A. Claims 1 and 38 are allowable. Claim 5 would be allowable if it was rewritten to depend solely from claim 1, or if the above issues regarding claim 5 were obviated.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 8 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647